Citation:

Azadbakht L, Mirmiran P, Hedayati M, Esmaillzadeh A, Shiva N, Azizi F. Particle size of LDL is affected by the National Cholesterol Education Program (NCEP) step II diet in dyslipidaemic adolescents. *Br J Nutr.* 2007 Jul; 98 (1): 134-139. Epub 2007 Apr 20.

PubMed ID: 17445337

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the effects of the National Cholesterol Education Program (NCEP) step II diet on LDL and HDL particle size in dyslipidemic adolescents.

Inclusion Criteria:

- Adolescents aged 10 years to 18 years
- Participants of the Tehran Lipid and Glucose Study
- Total cholesterol of at least 170mg per dL
- LDL-cholesterol of at least 110mg/dL.

Exclusion Criteria:

- Psychiatric problems
- Taking medications that affect nutrient metabolism, blood lipids, or blood pressure
- Taking vitamin or mineral supplements or antiacids containing magnesium or calcium
- Renal or liver disease

Description of Study Protocol:

Recruitment :Study participants were recruited as part of the Tehran Lipid and Glucose Study. Recruitment methods were not described.

Design: Randomized Controlled Trial.

- The patients were randomly assigned to two groups: the control group and the NCEP step II diet group.
- Twelve-hour fasting blood samples were collected at baseline and repeated every 6 weeks in

both groups.
- Information regarding age, smoking habits, physical activity, medical history, and current use of medications was obtained at baseline and every 2 weeks.

Blinding used (if applicable): Laboratory staff were blinded. Nutritionists were not blinded.

Intervention (if applicable):

- The control group was instructed to "eat as usual".
- The NCEP step II diet group was given individualized diets (based on energy needs) that were 30% total fat, less than 7% saturated fat, less than 200 mg cholesterol, less than 15% of energy as MUFA and less than 10% of energy as PUFA. Patients were visited every 2 weeks and were in touch with a nutritionist by phone every day. Each patient had to bring a 3 day diet record to the nutritionist every 2 weeks. A 7-day menu cycle was developed for each diet. The clinical center followed each patient every 2 weeks for the 3-month duration of the intervention.

Statistical Analysis:

- One way ANOVA and χ^2 tests were used to determine the significance of baseline differences between groups.
- Comparisons between the changes of the two groups were also assessed using ANOVA.
- Differences in lipid responses were evaluated in different weight status by Student's *t* test.

Data Collection Summary:

Timing of Measurements:

- The duration of the study was 3 months.
- Data (including blood pressure, weight, health, and dietary intake data) was collected every 2 weeks.
- Twelve-hour fasting blood samples were collected at baseline and repeated every 6 weeks in both groups.

Dependent Variables

- LDL-C particle size as measured by electrophoresis
- HDL-C particle size as measured by electrophoresis
- Total cholesterol (mg/dL) as measured by autoanalyzer
- LDL-cholesterol (mg/dL) as calculated by the Friedewald method
- HDL-cholesterol (mg/dL) as measured by autoanalyzer
- Height, weight, BMI

Independent Variables

- NCEP step II diet as measured by analysis of food records
- Control diet

Description of Actual Data Sample:

Initial N: Sixty adolescents were assessed for eligibility in the study. Fourteen were ineligible because they did not meet study protocol. The initial n was 46 subjects, 23 females and 23 males.

Attrition (final N): Two subjects dropped out, one in each group, making the final n = 44.

Age: 10-18 (mean of 14.5 years). Mean age of NCEP group was 14.4 years and control group was 14.6 years.

Ethnicity: Not specified

Other relevant demographics: 50% of participants were in junior high school and 50% were in high school.

Anthropometric measures:

- Mean BMI was 26.4 kg/m^2
- BMI of cases of 26.2 kg/m^2 and controls was 26.3 kg/m^2.
- Mean blood pressure of NCEP group was 110/69 mmHg and of the controls 112/70 mmHg.
- Baseline characteristics of these adolescents did not differ significantly across the NCEP step II and control diet groups

Location:Tehran, Iran

Summary of Results:

Key Findings:

- Significant reductions in total cholesterol (13 ± 4 versus -2 ± 0.3 mg/dL, P < 0.001) and LDL-C (-9 ± 2 versus 3 ± 0.6 mg/dl, P < 0.01) were seen among adolescents who consumed the NCEP step II diet.
- The NCEP step II diet significantly increased LDL-C particle size (1.7 ± 0.4 versus 0.1 ± 0.4 nm, P < 0.001).
- HDL particle size did not change significantly.
- Weight and physical activity did not significantly change during the study period.

Cardiovascular risk factors of adolescents at baseline, after 6 weeks and after 12 weeks of intervention, by diet groups (mean and SD)

	Control	Control	Control		NCEP step II	NCEP step II	NCEP Step II	
	Baseline Mean ± SD	6 weeks Mean ± SD	12 weeks Mean ± SD	p	Baseline Mean ± SD	6 weeks Mean ± SD	12 weeks Mean ± SD	p
Weight (kg)	63.0 ± 6	62.5 ± 6	62.3 ± 6	NS	63.2 ± 6	63.1 ± 6	63.0 ± 6	NS
Total Cholesterol (mg/dL)	221 ± 23	220 ± 24	219 ± 23	NS	219 ± 24	212 ± 22	206 ± 20	0.03
LDL-C (mg/dL)	141 ± 16	142 ± 16	144 ± 17	NS	143 ± 17	139 ± 16	134 ± 15	0.02
HDL-C (mg/dL)	38 ± 9	37 ± 9	38 ± 9	NS	39 ± 9	37 ± 8	36 ± 8	NS

LDL-C particle size (nm)	26.2 ± 3.3	26.3 ± 3.2	26.3 ± 3.3	NS	26.2 ± 3.5	27 ± 3.6	27.9 ± 3.9	0.03
HDL-C particle size (nm)	9.3 ± 1.8	9.2 ± 1.8	9.1 ± 1.7	NS	9.3 ± 1.7	9.4 ± 1.9	9.5 ± 1.8	NS

Other findings:

- Fiber content of the NCEP step II diet was higher than the control diet (29 grams vs 10 grams).
- The saturated fat intake of the step II diet was significantly lower than the controls (7 percent of energy vs 14 percent of energy).
- The total cholesterol intake of the step II diet was significantly lower than the control diet (183 milligrams vs. 311 milligrams)
- The monounsaturated fat intake of the step II was significantly higher than the controls (14 grams vs 9 grams).
- The NCEP step II diet did not change HDL levels.

Author Conclusion:

NCEP step II diet not only reduces the serum LDL concentration of hypercholesterolemic adolescents but also has a favorable effect on the LDL particle size distribution.

Reviewer Comments:

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes